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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/817,762	03/26/2001	Edgar P. Spalding	13238-00061	7874

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EXAMINER
IBRAHIM, MEDINA AHMED

ART UNIT	PAPER NUMBER
1638	13

DATE MAILED: 06/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/817,762	Spalding et al
Examiner	**Art Unit**
Medina Ibrahim	1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) X Responsive to communication(s) filed on *Mar 3, 2003* .

2a) X This action is **FINAL**. 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) X Claim(s) *1-6, 9-14, 17-24, and 28-31* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) X Claim(s) *1-4, 9-14, 17-24, and 28-31* is/are rejected.

7) X Claim(s) *5 and 6* is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____ .
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and or 121

Attachment(s)

3 Information Disclosure Statement s PTO 1449 Paper No s 6 Other

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant's response filed 03/03/03 in reply to the Office action mailed 10/2/02 and amendment B have been entered. Claim 27 is cancelled. Therefore, claims 1-6, 9-14, 17-24 and 28-31 are pending and are under examination.

All previous rejections and objections not stated below have been withdrawn.

Claim Rejections - 35 U.S.C. § 112, Scope of Enablement

1. Claims 9, 12, 17-19, 24 and 28-31 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the isolated nucleic acid sequence of SEQ ID NO:1 or 10 encoding SEQ ID NO:2 , an expression cassette comprising said nucleic acid sequence operably linked to a promoter, a plant or a plant cell transformed with said vector, does not reasonably provide enablement for any nucleic acid encoding any plant p-glycoprotein as recited in claim, the coding sequence of a p1PAC gene which is a part of SEQ ID NO:1 or 10, sequences that are 60% identical to the coding region of SEQ ID NO:1 or 10 and 70% or 80% identical to SEQ ID NO:2, sequences that hybridize to SEQ ID NO:1 or 10 or regions thereof under the defined hybridization conditions and encoding a p-glycoprotein, and transformed plant and plant cell comprising said sequences. This rejection is repeated for the

reasons of record as set forth in the Office action of 10/02/2002. Applicant's arguments filed 03/03/03 have been considered but are not deemed persuasive.

Applicant contends the Office action does not establish any grounds to support the conclusion that the claimed invention cannot be practiced without undue experimentation. Applicant relies upon the following points to support his position: 1) the question of enablement is a question of law, based on the analysis of several factors as determined in *In re Wands* and *In re Wright*, and that the law is clear that the specification need not teach each and every claimed limitation or what is well-known in the art. 2) It is known in the art that it is very common for a closely related plant species to have large divergences in sequences at the nucleotide level, due to codon degeneracy, and have 100% identity in the encoded protein. Applicant asserts the nucleic acid of the instant claims define variation that is within art-expected and art accepted norms. 3) the instant specification provides substantial guidance in identifying the nucleic acid by structure through restriction endonuclease mapping which is an art-recognized means of identifying a nucleic acid structure. 3) the cited references Broun et al and Lazar are not relevant in the claimed invention as they do not teach a plant p-glycoprotein and inducibility by NPPB. Applicant cites Science article to support the proposition that a proteins' amino acid may be altered by up to 70% and yet its 3D structure. Applicant finally argues that, given the disclosure of the structural limitations with respect to the required restriction endonuclease sites, and the functional

description will enable one of skill to make and use the claimed nucleic acids commensurate with the disclosure. Applicant urges that the rejection is withdrawn.

These arguments are not persuasive. Applicant correctly states that the specification is not required to disclose each and every claimed embodiment or what is well-known in the art. However, the law under 35 USC 112, 1st paragraph requires that the scope of the claims is commensurated with the enabling disclosure. In the instant case, the claimed invention is not supported by an enabling disclosure taking into account the *In re wand's* factors: The breadth of the claims encompasses nucleic acid sequences from any source that are at least 60% identical to the coding region of SEQ ID NO:1 or 10, sequences that hybridize thereto or specific fragments thereof under specified hybridization condition and encoding a p-glycoprotein, nucleic acid sequences encoding an amino acid sequence that is at least 70% or 80% identical to SEQ ID NO:2, the coding sequence of a p1PAC gene or a part thereof, and transgenic plant and plant cell comprising said sequences. The state of the prior art as exemplified by Broun and Lazar teaches that sequence identity does not necessarily mean similar function. No specific guidance has been provided regarding modifications that allow the claimed nucleic acid sequences to retain p-glycoprotein NPPB responsive activity. The prior art does not amend this deficiency. While P-glycoprotein encoding genes with function that varies from detoxification of drugs and toxins, cytochrome P450 activity, cell death and cell differentiation are known in the art, it is unclear if a nucleic acid

were well-known before Applicant's invention. Therefore, weighing all above factors, it is reasonable to conclude that one of skill in the art could not make and use the nucleic acid of claims 9, 12, 24, without undue experimentation. Claim 9 is included in the rejection because the specification does not provide guidance for primers and specific hybridization conditions for the isolation of the coding region of p1PAC genes from other species. Claim 12 is rejected because any "part" of SEQ ID NO:1 or 10 was not shown to encode the desired p-glycoprotein. Furthermore, no transgenic plant /plant cell/seed having enhanced resistance to xenobiotic compounds as a result of expressing the nucleic acid of claims 12 and 24 has been disclosed.

In addition, Applicant's assertion that the variation in the nucleic acid sequence of claims 12 and 24 is due to genetic codon degeneracy, and that the encoded proteins are expected to have 100% sequence identity is incorrect. The claimed invention is not limited to nucleic acid sequences from a closely related plant species or nucleic acid sequences encoding SEQ ID NO:2. The claims encompass variants and fragments of the disclosed sequences from any source which are not expected to encode proteins having 100% sequence identity to SEQ ID NO:2. Accordingly, the claimed invention is not enabled throughout the broad scope, as stated in the last Office action. The rejection is maintained.

With respect to Applicants arguments against Lazar and Broun, the references are relied upon because they both provide unpredictability not only in protein/DNA

and/or hybridizing property, alone. Applicant has provided no convincing evidence that the p-glycoprotein of the invention is comparable to the proteins described in Science (277:179, 1997, provided by Applicant) and not to the proteins described by Broun and Lazar.

Written Description

Claims 1-4, 9-14, 17-24 and 27-31 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is repeated for the reasons of record as set forth in the last Office action. Applicant's arguments have been considered but are not deemed persuasive.

Applicant's arguments are basically the following: the specification describes two gene sequences, a cDNA and the sequence of the encoded amino acid sequence, detailed restriction endonuclease cleavage maps, comparative analysis of related sequences from other organism, and a consensus sequence. The disclosure of NPPB-inducible p-glycoprotein encoding sequences with restriction maps and the functional information are sufficient to convey one of skill in the art that Applicant was in possession of the claimed invention at the time of filing (response, pg. 23-26).

These arguments are not persuasive. While restriction endonuclease mapping is

sequences are not limited to those described in the specification either by SEQ ID NO or by physical mapping. Claim 1 recites "cleavage sites.... for one or more restriction endonuclease" which includes fragments within SEQ ID NO:1 or 10 that are non-coding or regulatory regions and that are not sufficiently described in the specification. Claim 12 recites "a part" of SEQ ID NO:1 or 10 which reads on non-coding and regulatory regions that are not described in the specification. Further, it is unclear whether the consensus sequences described in Figures 1-4 is for all p-glycoproteins or specifically for those induced by NPPB. It is also noted that Claims 12 and 24, part (b, e-f) do not recite functional limitations. Consequently, in view of the above and the level of skill and knowledge in the art of plant p-glycoprotein responsive to NPPB, the claimed invention is not adequately described. Therefore, the rejection is maintained.

Remarks

SEQ ID NO:1 or 10 encoding SEQ ID NO:2 are free of the prior art of record.

Claims 5-6 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Papers relating to this application may be submitted to Technology Sector 1 by facsimile transmission. Papers should be faxed to Crystal Mall 1, Art Unit 1638, using fax number (703) 308-4242. All Technology Sector 1 fax machines are available to receive transmissions 24 hrs/day, 7 days/wk. Please note that the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30, (November 15, 1989).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Medina A. Ibrahim whose telephone number is (703) 306-5822. The Examiner can normally be reached Monday -Thursday from 8:00AM to 5:30 PM and every other Friday from 9:00AM to 5:00 PM .

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Amy Nelson, can be reached at (703) 306-3218.

Any inquiry of a general nature or relating to the status of this application should be directed to the receptionist whose telephone number is (703) 308-0196.

June 1, 2003
mai

ELIZABETH F. McELWAIN
PRIMARY EXAMINER
GROUP 1800